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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,411	08/23/2006	Ronald Bradley DeMattos	X16324	5484

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ELI LILLY & COMPANY
PATENT DIVISION
P.O. BOX 6288
INDIANAPOLIS, IN 46206-6288

EXAMINER	
AFREMOVA, VERA	
ART UNIT	PAPER NUMBER
1657	

NOTIFICATION DATE	DELIVERY MODE
10/07/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@lilly.com

Office Action Summary	Application No.	Applicant(s)	
	10/590,411	DEMATTOS ET AL.	
	Examiner	Art Unit	
	Vera Afremova	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 17-21 as amended (6/05/2009) are pending and under examination.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 17-21 remain rejected under 35 U.S.C. 103(a) as being unpatentable over US 7,195,761(Holtzman et al) and US 6,518,011 (Seiffert et al) as explained in the prior office action and repeated herein.

Claims are directed to a process for preparing an abeta antibody wherein the method comprises steps of expressing the antibody in cells that endogenously express abeta peptide; adding a beta or gamma secretase inhibitor to media used to grow the cells and purifying the antibody from the growth media wherein the purified antibody has no or low levels of endogenously produced abeta peptide. Some claims are further drawn to the use of mammalian cells including human cells and/or including CHO, HEK 293, PER.C6, and NS0 cells.

US 7,195,761(Holtzman et al) teaches a process for preparing an abeta antibody wherein the method comprises steps of expressing the abeta antibody in cells and purifying the abeta antibody from the growth media wherein the abeta antibody-containing product would be 99% pure (entire document including abstract and col.19, lines 15-50). The cited patent teaches that use of various mammalian and human cells including CHO cell lines and HEK or human

embryonic kidney cell lines (col. 19, lines 20-23) for expression and production of abeta antibody.

The method of US 7,195,761(Holtzman et al) does not include step of suppressing abeta peptide production with secretase inhibitor during *in vitro* cell culturing and abeta antibody production. However, the cited patent US 6,518,011 (Seiffert et al) teaches step of suppressing abeta peptide production or accumulation in the presence of gamma secretase inhibitors in an *in vitro* cell culture. The cells are human kidney cell lines HEK 292 that endogenously express abeta peptide (par. bridging col.14 and col.15).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to add step of suppressing accumulation or production of abeta peptide of US 6,518,011 to the method of making abeta antibody by cell engineered to express abeta antibody of US 7,195,761 with a reasonable expectation of success in producing abeta peptide pure preparations with no or low content of abeta peptide because it is known to use gamma secretase inhibitors for suppressing abeta peptide production and/or accumulation in an *in vitro* cell culture. One of skill in the art would clearly be motivated to suppress peptide production in cells modified to produce an antibody to this peptide for the expected benefits in avoiding interaction between peptide and antibody to this peptide.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented be the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Response to Arguments

Applicant's arguments filed 6/05/2009 have been fully considered but they are not found persuasive.

With regard to claim rejection under 35 USC § 103 applicants' main argument is that there is no suggestion to combine the teaching of cited patent US 7,195,761(Holtzman et al) as drawn to a process for producing abeta antibody by a recombinant cell culture with the teaching of the cited patent US 6,518,011 (Seiffert et al) as drawn to suppression of abeta peptide production in the presence of gamma secretase inhibitors in an *in vitro* cell culture because the problem of abeta peptide contamination of recombinantly produced anti-abeta-antibody is not recognized by the cited prior art. This argument is not found convincing because contamination of recombinant products by the host cell line products is always regarded as source of undesirable immunogenic side effects in vaccine preparations. The cited patent US 7,195,761(Holtzman et al) teaches production of 99% pure abeta antibody recombinant product and the cited patent US 6,518,011 (Seiffert et al) clearly teaches that the native abeta peptide production/accumulation is suppressed in the presence of gamma secretase inhibitors in an *in vitro* cell culture. Thus, one of skill in the art would clearly be motivated to suppress peptide production in cells modified to produce an antibody to this peptide for the expected benefits in avoiding interaction between peptide and antibody to this peptide.

Therefore, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary and the claims are properly rejected under 35 USC § 103.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber, can be reached at (571) 272-0925.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

September 30, 2009

/Vera Afremova/
Primary Examiner, Art Unit 1657